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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,892	10/01/2007	Christian Hansen	11591-008-999 (CAM: 78200	3750

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JONES DAY
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EXAMINER	
SOROUSH, ALI	
ART UNIT	PAPER NUMBER
1617	
MAIL DATE	DELIVERY MODE
02/16/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/590,892	HANSEN ET AL.	
	Examiner	Art Unit	
	ALI SOROUSH	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 November 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19 and 22-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19 and 22-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11232010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgement of Receipt

Applicant's response filed on 11/23/2010 to the Office Action mailed on 05/25/2010 is acknowledged.

Claim Status

Claims 1-19 and 22-32 are pending.

Claims 20 and 21 are cancelled.

Claims 2, 13, and 27 are currently amended.

Claims 30-32 are newly added.

Claims 1-19 and 22-32 have been examined.

Claims 1-19 and 22-32 are rejected.

Rejections and/or objections not reiterated from the previous Office Action are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 11/23/2010 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 1-19 and 22-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Little et al. (International Application Published Under the PCT WO 02/062351 A1, Published 08/15/2002) in view of Marie et al. (Mechanism of Action and Therapeutic Potential of Strontium in Bone, Published 08/08/2001).

A method of treating an osteonecrotic bone in disease comprising administering an effective dose of strontium-containing compound.

Little et al. teach the treatment and prevention of osteonecrosis by the administration of bisphosphonate. (See title and abstract). “Application of therapeutically effective amount of bisphosphonate will slow the resorption and collapse of the necrotic bone, limit the resorption of the metaphyseal bone and promote increased mineral content in the new bone forming in the lateral portion of the epiphysis. By preventing collapse of the necrotic bone and increasing the mechanical integrity of the new bone, a more spherical shape of the femoral head will be maitained." (See page 15, Lines 202-25). Little et al. teach that osteonecrosis can result from exposure to glucocorticoids or cytotoxic drugs. (See page 1, Lines 11-20).

Little et al. lacks a teaching wherein the composition comprises a strontium-containing compound.

Marie et al. teach that strontium compounds specifically strontium ranelate increases bone formation and reduces bone resorption, leading to increased bone mass and improved bone mechanical properties. (See title and page 127, column 2, Lines 1-13).

It would have been obvious to one of ordinary skill in the art to combine the teachings of Little et al. with Marie et al. One would have been motivated to do so because both Little et al. and Marie et al. are directed to treatment of bone conditions associated with loss of bone mass and mechanical properties. Furthermore, Little et al. and Marie et al. teach that both bisphosphonate and strontium ranelate act by

increasing bone formation and reducing bone resorption. Therefore, it would have been obvious one ordinary skill in the art that strontium ranelate would also be useful in the treatment of osteonecrosis.

Response to Applicant's Arguments

Applicant argues that Little et al. fails to provide motivation to use a compound other than a bisphosphonate for treating osteonecrosis. Applicant's argument has been fully considered but found not to be persuasive. Little et al. and Marie et al. both teach that bisphosphonate and strontium, respectively, are effective in increasing bone formation and reducing bone resorption. Therefore, both compositions are useful for the same purpose that is increasing bone formation and reducing bone resorption. It is therefore obvious to combine individual compositions taught to have the same utility to form a new composition for the very same purpose, which is increasing bone formation and reducing bone resorption (In re Kerkhoven, 205 USPQ 1069 (CCPA 1980)).

Applicant argues that one of ordinary skill in the art would not have been motivated to substitute strontium in Marie et al. for bisphosphonates of Little et al. since the compounds have such differing chemical structures. Applicant's argument has been fully considered but found not to be persuasive. The Examiner has not relied on Marie et al. to substitute one compound for another but rather to combine two compositions intended for the same use.

Applicant finally argues that Marie et al. and Little et al. are directed to differing medical conditions, osteoperosis and osteonecrosis, and therefore one of ordinary skill in the art would not be motivated to utilize strontium taught for treating osteoperosis for

the treatment of osteonecrosis. Applicant's argument has been fully considered but found not to be persuasive. Marie et al. and Little et al. teach that the underlying symptom that both are attempting to treat are the same, bone loss in each condition. While the reason for the bone loss is divergent in the teachings the means of treating the symptom can be the same. Marie et al. show that bisphosphonates are utilized in treating osteoperosis (page 121, column 2, Lines 1-5). Therefore, compounds useful in treating osteoperosis can be utilized in treating osteonecrosis where the symptom to be treated is bone loss. Therefore the rejection is maintained.

This is a new grounds of rejection.

2. Claims 1-19 and 22-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Little et al. (International Application Published Under the PCT WO 02/062351 A1, Published 08/15/2002) in view of Marie et al. (Mechanism of Action and Therapeutic Potential of Strontium in Bone, Published 08/08/2001) and Tsouderos et al. (US Patent 5856356, Published 01/05/1999).

A method of treating an osteonecrotic bone in disease comprising administering an effective dose of strontium-containing compound. Wherein the strontium containing compound is strontium malonate.

The teachings of Little et al. and Marie et al. are discussed above.

Marie et al. lacks a teaching wherein the strontium compound is strontium malonate.

Tsouderos et al. teach strontium salts and pharmaceutical compositions thereof (title). Preferred salts include strontium malonate and strontium ranelate (column 1, lines 59-67 and column 2, lines 1-18).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to substitute strontium malonate for strontium ranelate, since Tsouderos et al. show that they are suitable alternatives and Marie et al. teach that any strontium compound would increase bone formation and reduce bone resorption.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALI SOROUSH whose telephone number is (571)272-9925. The examiner can normally be reached on M-F (9am-6pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fereydoun G. Sajjadi can be reached on (571)272-3311. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/A. S./
Examiner, Art Unit 1617

/KARLHEINZ R SKOWRONEK/
Primary Examiner, Art Unit 1631

February 11, 2011